REMARKS

Reconsideration of this application is requested. Claims 1-5 and 8-11 will be active in the application subsequent to entry of this Amendment.

The examiner's attention is directed to an Information Disclosure Statement filed January 23, 2003, providing the results of a search conducted in the counterpart European application. As this Information Disclosure Statement was filed within three months of the mailing date of the European action, no additional fee is required. The examiner is requested to consider the documents, all U.S. patents, identified in the Information Disclosure Statement and to make the Information Disclosure Statement of record in this application.

The claims have been amended in order to more particularly point out and distinctly claim that which applicants regard as their invention, and to direct them to preferred aspects of the invention. More specifically, claims 6 and 7 have been incorporated into claim 1 and the dependencies of the remaining claims adjusted in order remove multiple dependencies and to adjust for the deletion of claims 6 and 7.

Claims 1-5 and 7-9 were rejected on the basis of alleged anticipation by Schaffer et al U.S. 4,508,723. The amendments to the claims, which include combining the subject matter of claim 6 under claim 1, resolve the anticipation rejection set out on page 2 of the Official Action. This leaves for consideration the rejections stated on pages 3 and 4 of the Official Action. All of the original claims are rejected as being unpatentable over

Schaffner et al (U.S. Patent No. 4,508,723) or Lang (U.S. Patent No. 4,826,832). Applicants disagree.

First of all, applicants emphasize that both Schaffner et al and Lang basically relate to penem compounds, hence they do not relate to a more general fast-disintegrating oral granular composition as in the present invention.

Schaffner et al describe the fact that penem compounds can be formulated using additives including sucrose and mannitol, and that the formulation may be a syrup. Further, Lang describe that penem compounds can be formed into various types of formulations, and with various combinations of sucrose or mannitol. However, the disclosure of Schaffner et al and Lang are merely general information on typical formulations and additives and are not specifically addressed to achieving fast-disintegrating oral pharmaceutical compositions.

In contrast, the present invention specifically relates to a granular composition which contains an active ingredient selectable from various types of actives and can be easily suspended or dissolved at the time when an oral administration is needed. Thus, as applicants explain in their specification "the inventors studied carefully the development of a widely applicable technique for use in preparing oral granular formulations; with the resulting formulations having good handling properties, and able to rapidly disintegrate or dissolve, either in the mouth during administration, or when they are dissolved or suspended before use. As a result, the inventors accomplished the present invention on the basis of the finding that oral granular formulations showing rapid disintegration or

dissolution in the mouth during administration or when they are dissolved or suspended before use can be prepared by granulation with sucrose with a reduced amount of binders."

The most important feature of the present invention is that sucrose is present in an amount of at least 30% by weight based on the total weight of the composition. By preparing granules with such a high sucrose content, it was surprisingly found that granulation was possible with a reduced amount of binders or even in the absence of any binder (binder is omitted), and yet the resulting granules are fast-disintegrating and promptly disperse or solubilize in water.

Schaffner et al and Lang do not suggest anything about the use of sucrose in an amount 30% or greater in preparing a granular pharmaceutical composition with a reduced amount of, or even without, binders to provide fast-disintegrating granules which are easily soluble or dispersible in water. Thus, applicants respectfully submit that the present invention is not obvious over Schaffner et al and Lang, singly or combined in any manner.

It is applicants' position that the cited documents are directed to specific products and not concerned with more generalized formulations. Nor do these citations address the task of providing a fast-disintegrating oral pharmaceutical composition which is prepared right by granulation and contains at least 30% by weight sucrose and provides a dosage form to be dissolved or suspended before use.

The citations merely mention fillers or "adjuncts" which may be selected from a far ranging group of possibilities. The citations do not address providing a fast-disintegrating oral pharmaceutical composition and thus do not render obvious applicants' claims 1-5 and 8-11.

Reconsideration and favorable action are solicited.

Respectfully submitted,

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